

Claims:

The following listing of Claims will replace all prior versions and listings of Claims in the Application

1. (currently amended) An orally deliverable pharmaceutical composition comprising a drug of low water solubility and a pregelatinized starch having low viscosity and/or exhibiting a multimodal particle size distribution, **said pregelatinized starch selected on the basis of determination of low viscosity and/or a particle size test.**
2. (original) The composition of claim 1 that is in a form of a tablet or capsule.
3. (original) The composition of claim 1 wherein the drug is a selective cyclooxygenase-2 inhibitory drug.
4. (original) The composition of claim 3 wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methanesulfonyl)phenyl]-2-cyclopenten-1-one, 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methanesulfonyl)phenyl]-3-(2H)-pyridazinone, and pharmaceutically acceptable salts and prodrugs thereof.
5. (original) The composition of claim 3 wherein the selective cyclooxygenase-2 inhibitory drug is valdecoxib.
6. (original) The composition of claim 5 that is in the form of a tablet or capsule, wherein the valdecoxib is present in an amount of about 1 mg to about 100 mg.
7. (original) The composition of claim 6 wherein the valdecoxib is present in an amount of about 5 mg to about 40 mg.
8. The composition of claim 5 wherein the valdecoxib has a D₉₀ particle size less than about 75 µm.
9. The composition of claim 1 wherein the pregelatinized starch exhibits a shear stress

of not more than about 1 Pa at a shear rate of 20 s^{-1} .

10. The composition of claim 9 wherein the pregelatinized starch further exhibits a shear stress of not more than about 2 Pa at a shear rate of 60 s^{-1} .

11. The composition of claim 10 wherein the pregelatinized starch further exhibits a shear stress of not more than about 3 Pa at a shear rate of 100 s^{-1} .

12. The composition of claim 1 wherein the pregelatinized starch exhibits a shear stress of not more than about 0.75 Pa at a shear rate of 20 s^{-1} .

13. The composition of claim 12 wherein the pregelatinized starch further exhibits a shear stress of not more than about 1.5 Pa at a shear rate of 60 s^{-1} .

14. The composition of claim 13 wherein the pregelatinized starch further exhibits a shear stress of not more than about 2.5 Pa at a shear rate of 100 s^{-1} .

15. The composition of claim 1 wherein the pregelatinized starch exhibits a shear stress of not more than about 0.5 Pa at a shear rate of 20 s^{-1} .

16. The composition of claim 15 wherein the pregelatinized starch further exhibits a shear stress of not more than about 1 Pa at a shear rate of 60 s^{-1} .

17. The composition of claim 16 wherein the pregelatinized starch further exhibits a shear stress of not more than about 1.5 Pa at a shear rate of 100 s^{-1} .

18. The composition of claim 1 wherein the pregelatinized starch exhibits a multimodal particle size distribution.

19. The composition of claim 1 wherein the pregelatinized starch exhibits a bimodal particle size distribution.

20. The composition of claim 1 wherein the starch is present in an amount of about 1% to about 50% by weight of the composition.

21. The composition of claim 1 wherein the starch is present in an amount of about 2.5% to about 30% by weight of the composition.

22. The composition of claim 1 that is in a form of a tablet, further comprising one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition.

23. The composition of claim 1 that is in a form of a tablet, further comprising one or more excipients selected from the group consisting of lactose monohydrate, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

24. (withdrawn) A process for preparing an orally deliverable pharmaceutical composition, the process comprising a step of selecting a pregelatinized starch having low viscosity and/or exhibiting a multimodal particle size profile, and a step of admixing the selected pregelatinized starch with a drug of low water solubility to provide an admixture.

25. (withdrawn) The process of claim 24 wherein the drug is a selective cyclooxygenase-2 inhibitory drug.

26. (withdrawn) The process of claim 25 wherein the selective cyclooxygenase-2 inhibitory drug is valdecoxib.

27. (withdrawn) The process of claim 24, further comprising a step of wet granulating the admixture with one or more diluents, a step of drying the resulting granules, and a step of compressing the resulting dry granules to form a tablet.

28. (withdrawn) A method of improving drug release rate consistency among pharmaceutical tablets prepared within a single manufacturing campaign, said tablets comprising pregelatinized starch and a drug having low water solubility, wherein the method comprises a step of selecting, for use in said tablets, a pregelatinized starch having low viscosity and/or exhibiting a multimodal particle size distribution.

29. (withdrawn) A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, the method comprising orally administering to the subject a composition of claim 3 once or twice a day.